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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,100	09/24/2003	Kenneth D. Fine	FINE 01936 C1US	7188

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STORM LLP
BANK OF AMERICA PLAZA
901 MAIN STREET, SUITE 7100
DALLAS, TX 75202

EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,100	FINE, KENNETH D.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 35-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

DETAILED ACTION

1. The amendment dated 04 December 2006 has been received. Claims 1-14 and 35-37 are pending.

2. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims and/or arguments.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,667,160. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a method for diagnosing an immunological food

sensitivity comprising the steps of collecting a fecal sample, screening the fecal sample to detect the presence of an IgA antibody to a particular food substance; and diagnosing an immunologic food sensitivity based on the presence of the antibody. Even though the '160 patent does not specifically teach the diagnosing an ailment related to the food sensitivity, this ailment can been seen as an obvious allergic reaction to certain type of food.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-14 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting immunological food sensitivity to a specific food by detecting IgA to said food, does not reasonably provide enablement for diagnosing any and *all* ailments related to the immunological food sensitivity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teaches the detection of antigliadin IgA antibodies and antitissue transglutaminase IgA in fecal samples and relating the presence of these IgAs to celiac spruce due to allergies to dietary glutens. However, the specification does not

teach the diagnoses of immunological food sensitivity based on the presence of IgA to specific foods, and relating to the food sensitivity to *any and all* ailments such as claimed.

The claims broadly recite the detection of IgA to any and all food substances and if these IgAs are detected, a diagnosis of the sensitivity to that particular food is made. This is supported by the specification. However, the claim also broadly recites that once a diagnosis of food sensitivity is made, it can be related to an ailment and broadly claims ailments such as irritable bowel syndrome, microscopic colitis, chronic diarrhea, chronic liver disease, alcoholism, etc. This portion of the claims does not have support in the specification as originally filed. Nowhere in the specification is there a disclosure of how specific food allergies can be related to alcoholism, for example.

The development of any suitable diagnostic assay requires a number of considerations. Mainly, (1) the sensitivity of the assay; (2) the true-positive test rate; (3) the false-negative test rate; (4) the specificity, or percentage of patients without the disease who will display a negative results; (5) the true-negative test rate; (6) the false-positive test rate; (7) the predictive value, or the probability that the test result is correctly indicating the presence or absence of the disease; (8) the prevalence, or number of patients in any given population that have the disease in question; (9) the efficiency or percentage of all results that are true; (10) the accuracy of the recited diagnostic assay. None of these parameters are addressed in the instant specification.

According to Strongin (1993, "Sensitivity, Specificity, and Predictive Value of Diagnostic Tests: Definitions and Clinical Applications", in Laboratory Diagnosis of Viral Infections, Lennette, e., ed., Marcel Dekker, Inc., New York, pp. 211-219), in addition to the above characteristics, additional considerations must also be examined to enable the clinician to practice the invention including assessment of the following: (1) when is the maximum sensitivity desired?; (2) when is the maximum specificity desired?; (3) when is the maximum efficiency desired?; (4) How is the maximum sensitivity or specificity achieved?; (5) how is the predictive value maximized? An essential understanding of these factors is required to enable the skilled artisan to accurately use and interpret any given diagnostic test. Since the specification lacks any teaching of how the diagnostic tests were performed, or any information regarding the patients from which the samples were taken, and whether any considerations were given to any of the characteristics state above, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

The specification lacks proper guidance to enable one skill in the art to determine the incidence of disease as related to the presence or absence of a specific food allergy. The specification further lacks proper guidance to enable one skilled in the art to distinguish between any and all disease states as claimed. Which of the many food allergies a person suffers from is the result of which specific ailment? No guidance is given for this diagnosis. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may

not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001. That requirement has not been met in this specification with respect to a method for diagnosing an ailment by detecting IgA to a specific food.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-11 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas et al. (Clinical Chemistry. Vol. 39, No. 4, pages 696-967. 1993).

Haas discloses an ELISA for fecal AGA IgA in patients suffering from celiac disease. Collected samples are frozen before use and reconstitute in buffer. Supernatant obtained by centrifugation was used to determine IgA using a commercial sandwich ELISA assay.

Even though Haas does not specifically teach using a sample of about 20g, nor does it disclose the consistency of the fecal sample, such a sample is seen to be obvious because it is no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. Since Applicant has not disclosed that the specific limitations recited in the instant claims are for any particular purpose or solve any stated problem and the prior art as well as the specification, teaches that other sample sizes may be used, and the amount is often varied according to the sample being analyzed, any appropriate amount of a testing portion depends on the requirements of an assay, appears to work equally well, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by Haas by normal optimization procedures known in the art. Furthermore, even though the reference does not specifically state the consistency of the fecal sample, one of ordinary skill in the art would have had a reasonable expectation of success in detecting analytes in samples with varied amount of solid to liquid material. It would appear that the make-up of the fecal sample does not negatively or positively impact a method of detecting any antibodies that may be present in them as alluded to the prior art of record.

9. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haas as applied to claim1-11 and 35-37 above, and further in view of Kolmannskog et al (Int. Archs Allergy Appl. Immun. Vol. 76. Pages 133-137. 1985.)

Haas differs from the instant invention in failing to teach the use of freeze-dried fecal sample.

Kolmannskog discloses the preparation of fecal samples for use in the detection of IgA, IgG and IgE as well as other substances. Kolmannskog discloses extracts of freeze-dried feces reconstituted in phosphate-buffered saline and the supernatant was used in the assay.

It would have obvious to one of ordinary skill in the art at the time the invention was made to use the freeze-dried sample of Kolmannskog in the method of Haas because such preparation of samples are well known in the art.

Response to Arguments

10. Applicant's arguments with respect to the rejection of claims 1-5, 8-10, 12-14 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Kolmannskog have been fully considered and are persuasive. The rejection of these claims has been withdrawn.

Applicant is correct in that Kolmannskog does not specifically discloses that the IgA detected are to a specific food substance. Instead, Kolmannskog discloses the detection of total IgA in a fecal sample

The argument that Haas does not teach or suggest the step of diagnosing the immunological food sensitivity based on the presence of the antibody is not persuasive. Haas discloses the diagnosis of celiac disease based on the detection of serum AGA IgA and further teaches the correlation between serum AGA IgA to fecal AGA IgA. Since it is well known that antigliadin IgA antibodies is diagnostic for dietary gluten sensitivity, Haas clearly teaches diagnosing immunological food sensitivity based on the presence of AGA IgA.

The argument with respect to the double patenting rejection is acknowledge. However, as of the date of this office action, a terminal disclaimer has not been received nor approved. Therefore, the ODP rejection is maintained until a TD is received and approved.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
2/26/07